provisions of this act, CDC funded 5 CADDRE centers including the California Department of Health and Human Services, Colorado Department of Public Health and Environment, Johns Hopkins University, the University of Pennsylvania, and the University of North Carolina at Chapel Hill. CDC National Center for Birth Defect and Developmental Disabilities will participate as the 6th site. The multi-site, collaborative study will be an epidemiological investigation of possible causes for the autism spectrum disorders.

Data collection methods will consist of the following: (1) Medical and educational record review of the child participant; (2) medical record review of the biological mother of the child participant; (3) a packet sent to the participants with self-administered questionnaires and a buccal swab kit; (4) a telephone interview focusing on pregnancy-related events and early life history (biological mother and/or primary caregiver interview); (5) a child development interview (for case participants only) administered over the telephone or in-person; (6) a developmental and physical exam of the child participant; (7) biological sampling of the child participant (blood and hair); and, (8) biological sampling of the biological parents of the child participant (blood only). OMB clearance is requested for the self administered questionnaires and buccal swab kit, the primary caregiver interview, and the child development interview. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Survey	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Cases:				
—Self administered questionnaires and buccal swab kit	644	1	3.0	1932
—Primary caregiver interview	644	1	40/60	429
—Child development interview	644	1	3.0	1932
Controls:				
—Self administered questionnaires and buccal swab kit	1288	1	3.0	3864
—Primary caregiver interview	1288	1	40/60	859
—Child development interview	1288	1	1.0	1288
Total				10,304

Dated: June 21, 2005.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–05–0010]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–371–5983 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

The National Birth Defects Prevention Study (OMB 0920–0010)—Extension—The Division of Birth Defects and Developmental Disabilities (DBDDD), National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC has been monitoring the occurrence of serious birth defects and genetic diseases in Atlanta since 1967 through the Metropolitan Atlanta Congenital Defects Program (MACDP). The MACDP is a population-based surveillance system for birth defects in the 5 counties of Metropolitan Atlanta. Its primary purpose is to describe the spatial and temporal patterns of birth defects occurrence and serve as an early warning system for new teratogens. From 1993 to 1996, the Division of Birth Defects and Developmental Disabilities (DBDDD) conducted the Birth Defects Risk Factor Surveillance (BDRFS) study, a case-control study of risk factors for selected birth defects. Infants with birth defects were identified through MACDP and maternal interviews and clinical/laboratory tests were conducted on approximately 300 cases and 100 controls per year. Controls were selected from among normal births in the same population. In 1997 the BDRFS became the National Birth Defects Prevention Study (NBDPS). The major components of the study did not change.

The NBDPS is a case-control study of major birth defects that includes cases identified from existing birth defect

surveillance registries in ten states (including metropolitan Atlanta). Control infants are randomly selected from birth certificates or birth hospital records. Mothers of case and control infants are interviewed using a computer-assisted telephone interview. Parents are asked to collect cheek cells from themselves and their infants for DNA testing. Information gathered from both the interviews and the DNA specimens will be used to study independent genetic and environmental factors as well as gene-environment interactions for a broad range of carefully classified birth defects.

This request is submitted to obtain OMB clearance for three additional years. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of burden	Number of respondents	Frequency of response	Average burden/response (in hours)	Annual burden (in hours)
NBDPS case/control interview	400	1	1	400
Biologic specimen collection	1,200	1	10/60	200
Total				600

Dated: June 21, 2005.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Augmenting Laboratory Outcomes in HIV Assessment (ALOHA)

Announcement Type: Supplemental (04017).

Funding Opportunity Number: AA120.

Catalog of Federal Domestic Assistance Number: 93.944.

Key Dates:

Application Deadline: August 5, 2005.

I. Funding Opportunity Description

Authority: This program is authorized under sections 317(k)(2) and 318b of the Public Health Service Act (42 U.S.C. Sections 247b(k)(2) and 247c), as amended.

Purpose: CD4+ T-lymphocyte (CD4) and viral load (VL) tests are used to stage disease and, when opportunistic infections (OI) are present, to guide therapeutic decisions. Because CD4 and VL testing should be performed throughout the course of HIV disease, reporting of these lab tests has been used as a marker for whether HIV-infected persons are receiving healthcare. Augmenting Laboratory Outcomes in HIV Assessment (ALOHA) will augment routine HIV/AIDS surveillance data collection for the purpose of assessing the completeness and validity of laboratory (*i.e.*, CD4 count and VL) and OI information. This will be accomplished by the following:

1. Assessing the stage of HIV disease at initial diagnosis among a cohort of newly diagnosed HIV-infected persons, over the age of 13, using routine and augmented laboratory and clinical information.

2. Better characterizing CD4 count and VL, and correlating this laboratory information with available data on OIs. If, after complete enumeration of lab and OI information, OIs add little to nothing to help stage HIV disease, then future surveillance practices may be streamlined.

3. Identifying surveillance practices (*e.g.*, laboratory reporting requirements, electronic lab reporting, and program policies or organization) that affect the completeness and accuracy of surveillance laboratory data.

4. Assessing lab reporting as a marker for access and adherence to care following HIV diagnosis.

5. Identifying correlates for not being in care, as indicated by the presence or absence of laboratory reports.

6. Systematically evaluating the availability of clinical and laboratory data on the prevalence of common co-morbid conditions (*e.g.*, hepatitis B, hepatitis C, tuberculosis, and cancer) that are associated with risk factors for HIV infection and influence the clinical course of HIV disease. Data on these conditions will be compared to levels of CD4 and VL to assess the effects of co-morbid conditions on levels of immunosuppression at the time of HIV diagnosis.

A variety of HIV/AIDS reporting areas with different surveillance practices and procedures will be sought for ALOHA. This project will attempt to include an area that currently warehouses lab results, specifically CD4, in a separate lab results database, and does not report this information to the national HIV/AIDS surveillance system. The completeness of reporting for CD4 results will be assessed to determine if these reports truly indicate access to care. This proportion has not been reliably estimated by national surveillance data. Some reporting areas report a high proportion (greater than 75 percent) of newly diagnosed cases with CD4 and/or VL results within 12 months of diagnosis.

The factors that contribute to the ability of lower morbidity areas to report completely has not been fully examined, but may be due to their ability to conduct active case finding and medical record abstraction. These practices may have national surveillance policy implications. Since lab reporting data is critical to the expectations of the Morbidity Monitoring Project (MMP), an area will be sought to provide validation of lab reporting as a marker for receiving health care, and to collect information about reasons for no lab testing and the inability to link a person to care.

Lastly, ALOHA will include at least one area that will match its HIV/AIDS case registry to infectious disease databases to identify, apart from medical record review, OIs that occurred six months before and after HIV diagnosis. Examples of these databases include the National Electronic Disease Surveillance System (NEDSS); cancer, hepatitis or tuberculosis registries; or prescription medication databases (*e.g.*, Medicaid or AIDS Drug Assistance Program).

As part of this project, participating areas will conduct their usual surveillance activities for information on CD4 and VL lab results and OIs. These activities include active case surveillance, medical record review and data extraction for newly diagnosed cases (over the age of 13). When no lab result is received by the HIV/AIDS surveillance program, ongoing active case follow-up will be needed to determine case disposition and record specific categorical information, such as